

# **EXHIBIT D**

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard, Mail Stop C2-21-16  
Baltimore, Maryland 21244-1850



**Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group**

June 10, 2019

John C. Bostic  
Assistant United States Attorney  
Northern District of California  
150 Almaden Boulevard, Suite 900  
San Jose, California 95113  
John.Bostic@usdoj.gov

Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Mr. Bostic:

This letter responds to your letter to me dated May 9, 2019 requesting access to certain categories of documents in connection with the above-referenced case. CMS has already expended significant resources to identify, search, collect, and produce over 260,000 pages to DOJ in this litigation and to respond to Mr. Balwani's September 14, 2018 subpoena in *SEC v. Balwani*, Case No. 18-cv-01602-EJD (SEC-Balwani Subpoena). The categories of documents you requested overlap significantly with DOJ's prior document requests during the investigation and with the categories of documents requested in the SEC-Balwani Subpoena. CMS is preparing a production in *SEC v. Balwani* pursuant to a May 30, 2019 Protective Order governing CMS productions in that matter. CMS can provide DOJ with a copy of the agency's production in the civil case once it is complete and after a Protective Order is entered in the criminal case.

To the extent your document requests seek CMS internal email, the agency is willing to produce responsive documents between September 1, 2013 and December 31, 2016 on the condition that an acceptable Protective Order is entered in the criminal matter. CMS does not construe DOJ's requests to include documents protected by the attorney-client or work product privileges and CMS does not plan to produce documents protected by those privileges.

CMS's response to each category of document requests is explained below.

- 1. Any and all correspondence or communications regarding Theranos between the federal government and John Carreyrou, The Wall Street Journal, or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;**

CMS collected and reviewed external communications between CMS and the media about Theranos between September 1, 2013 and December 31, 2016 to respond to the SEC-Balwani Subpoena and is in the process of preparing a production of these documents. This effort

encompasses your request for communications between CMS and John Carreyrou and/or The Wall Street Journal. CMS will provide DOJ with a copy of the future civil production once it is complete and after a Protective Order is entered in the criminal matter.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

- 2. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding Theranos' Clinical Laboratory Improvement Amendments ("CLIA") compliance during the time period of the charged conspiracies, including but not limited to those that concern the 2015 CLIA survey of Theranos;**

CMS has already produced a large volume of documents responsive to this category of documents to DOJ, including, but not limited to, CMS CLIA group communications with Theranos, communications about meetings or calls with Theranos, documents and communications regarding Theranos's compliance with federal CLIA regulations, the CLIA surveys of the Theranos California and Arizona labs, CMS surveyor notes, CMS Form 2567s, Theranos's Plan of Correction and exhibits, and complaints CMS received about Theranos labs.

CMS identified, collected, and reviewed external communications between additional CMS custodians selected by Mr. Balwani and Theranos between September 1, 2013 and December 31, 2016 to respond to the SEC-Balwani Subpoena and is in the process of preparing a production. CMS will provide DOJ with a copy of the future civil production once it is complete and after a Protective Order is entered in the criminal matter.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

- 3. Any and all correspondence or communications regarding Theranos between the government and any clinical laboratory company or association affiliated with clinical laboratories (including but not limited to LabCorp, Quest Diagnostics, and the American Clinical Lab Association), or their employees, agents, or counsel, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same;**

The CMS CLIA group does not generally communicate with third parties about the CLIA compliance of particular laboratories. The agency conducted a limited search for communications between the CMS CLIA group and LabCorp, Quest Diagnostics, or the American Association of Clinical Chemistry (AACC) to confirm this practice in response to the SEC-Balwani Subpoena. The search produced a few emails to or from AACC that are all form marketing emails or emails about attending the AACC Annual Scientific Meeting. CMS is in the process of preparing a production in the civil case that will include these documents and will provide DOJ with a copy once it is complete and after a Protective Order is entered in the criminal matter.

- 4. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the FDA's determination of the type of FDA approval required for Theranos' proprietary technology;**

CMS has few, if any, documents responsive to category four. Whether Theranos's proprietary technology required FDA approval was entirely an FDA determination. CMS already produced the few communications between the CMS CLIA group and the FDA about Theranos to Mr. Balwani in response to the SEC-Balwani Subpoena. CMS will provide a copy of this production to DOJ.

CMS also conducted a search for communications between additional CMS custodians selected by Mr. Balwani and the FDA during the time period September 1, 2013 to December 31, 2016 to complete its response to the SEC-Balwani Subpoena. CMS is currently reviewing the search results for responsive, non-privileged documents and plans to include these documents in the future production in the civil case. CMS will provide DOJ with a copy of that future production once it is complete and after a Protective Order is entered in the criminal matter.

**5. Any and all FBI 302s or other agency ROIs memorializing government communications with witnesses, and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency correspondence) regarding same; and**

CMS does not have documents responsive to category five.

**6. Any and all government documents, communications, correspondence, notes, or recordings (including intra-agency and/or inter-agency communications) regarding the 2013 CLIA survey of Theranos.**

CMS already produced to DOJ the relevant documents pertaining to the 2013 Theranos CLIA survey that CMS could pull from its system.

The 2013 Theranos CLIA survey was a routine survey performed by California Department of Public Health's California Laboratory Field Services (CDPH). State agencies do not usually communicate with CMS when performing routine CLIA surveys. The CMS CLIA group is not aware of any email communication with CDPH about the 2013 survey.

CMS will identify, collect, review, and produce responsive internal communications after an adequate Protective Order is entered in the criminal matter.

CDPH has located eight documents related to the federal 2013 Theranos CLIA Survey. The CDPH surveyor notes from the 2013 survey are no longer available. CDPH is not aware of any internal communications or written communications with CMS regarding the 2013 Theranos CLIA survey. *See* Attachment A, Declaration of Donna McCallum, June 3, 2019. These documents will be included in the production CMS is preparing in response to the SEC-Balwani Subpoena. CMS will provide DOJ with a copy of that future production once it is complete and after a Protective Order is entered in the criminal matter.

CMS is committed to working with you to produce documents responsive to your requests as detailed above. Please contact CMS counsel to discuss this matter further.

Sincerely,

*Karen W. Dyer*

Karen W. Dyer  
Director  
Division of Clinical Laboratory Improvement and Quality  
Centers for Medicare & Medicaid Services